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A recent workshop discussed characteristics of nonprescription drugs that may be considered “candy-like,” potentially resulting in inadvertent overdose in young children.

Pediatricians encouraged to join FDA workshops on pediatric drug development

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Food and Drug Administration

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The Food and Drug Administration (FDA) often contends with challenging issues that confound the development and use of pediatric therapeutics. To address these challenges, the FDA organizes public workshops that aim to analyze issues from multiple viewpoints and to discuss and advance potential solutions.

The FDA frequently collaborates with nonprofit organizations, academia and public-private partnerships to co-host these workshops, which bring together clinicians, researchers, patients, caregivers, advocates, regulators, the pharmaceutical industry and others. Pediatricians are encouraged to participate and share their expertise on these complex issues.

On Sept. 6, the FDA will host a workshop in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) to discuss ways to enhance enrollment of historically underrepresented populations in pediatric clinical trials. One goal of the workshop is to solicit input from stakeholders on how to ensure studies reflect the diversity of the population expected to use a drug or biologic, if approved. In addition to providing access to investigational therapies, this is crucial for identifying potential differences in safety or efficacy and helping reduce disparities in health outcomes.

Other recent workshops have covered topics such as:

- understanding the clinical impact on the developing fetus and newborn infant exposed in utero to drugs and biologics with immunosuppressive properties (July 2024, convened in partnership with M-CERSI),https://bit.ly/3Wlociq,
- clinical trial design, including endpoints, study population and comparators, for development of drugs to treat congenital cytomegalovirus infection and neonatal enteroviral sepsis (May 2024), https://bit.ly/3SnQNm5,
- innovative approaches to improve dosing recommendations for pediatric patients with renal impairment (November 2023, convened in partnership with M-CERSI), https://bit.ly/3A64XSv,
- defining characteristics of nonprescription drugs that may be considered “candy-like,” potentially resulting in inadvertent overdose in young children (October 2023, convened in partnership with M-CERSI), https://bit.ly/3zWlibk, and
- measuring clinical benefit in neonatal randomized clinical trials (March 2023, convened in partnership with the Duke-Margolis Center for Health Policy), https://bit.ly/3LCSok9.

The workshops typically are announced through the *Federal Register* as a “Notice” and posted at https://bit.ly/3WzSY8x. Meeting materials and recordings, when available, can be found on the meeting websites.

The FDA's Office of Pediatric Therapeutics and Office of New Drug's Division of Pediatrics and Maternal Health contributed to this article.

Resources

- CERSI workshops
- FDA workshops to advance development of medicines for children
- To find a *Federal Register* Notice for upcoming FDA workshops, visit https://bit.ly/3zPvNhG and select the current year as the Publication Date, Food and Drug Administration as the Agency and Notice as the Document Category.
- Information on how to use Regulations.gov